510(k) Summary
as required by 21 CFR 807.92(c)

Device Name	Charter™ Guidewire	
Submitters name/contact details	Brivant Ltd, Parkmore West Business Park, Galway, Ireland Contact Details: Tomas Furey Operations Manager, Tel: +353 91 385037 Fax: +353 91 766598	
Summary Preparation Date	10th November 2010	
Device Name & Classification	Trade Name:	Charter™ Guidewire
	Common Name:	Guidewire
	Classification Name:	Catheter, Guidewire
	Device Classification:	Class II, 21 CFR §870.1330
	Product Code:	DQX
Intended Use	Intended Use: The Charter™ Guidewires are intended for use in the coronary and peripheral vasculature. Contraindications: The Charter™ Guidewire is not intended for use in the cerebral vasculature. Patients judged not acceptable for percutaneous intervention (PCI)	
Device Description	The Navilyst Medical Guidewire is a disposable medical device designed for single use only. It consists of a PTFE coated 140cm or 180cm, 0.014" or 0.018" diameter stainless steel core wire, one end of which is reduced in diameter over a 43cm approx. segment in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and can be varied to produce various levels of support. The distal part of the reduced section is covered with a 3cm, 0.010" platinum tungsten spring coil. This provides greater visibility on x-ray equipment. A 39cm approx. length of black / grey Estane 88A radiopaque heat shrink polymer tubing is applied over the tapered distal end of the wire and ground to form a constant outer diameter, OD, equivalent in diameter to the main core body. Coatings are placed on the device to improve the lubricity and ease in its advancement through the guide catheter and the blood vessel	

Predicate Devices

Manufacturer	510k	Date
Brivant Ltd, Brivant Guidewire	K060551	07 Jun 2006
Brivant Ltd, Streamer Guidewire	K083094	07 July 2009
Brivant Ltd, Courier Guidewire	K073082	09 Jan 2008

Principle of Operation	The Charter™ Guidewire is operated manually by a manual process
Comparison of Technological Characteristics	The Charter™ wire has minor differences in construction to the approved Brivant Guidewire. These include - Same diameter range as predicate devices - Same basic construction technology as the predicate devices. - Different polymer and hydrophilic coating materials to the predicate devices providing improved radiopacity. - Slightly shorter overall length than predicate devices. - Minor differences in profiles of the distal tip area of the guidewire changes to meet customer performance requirements. These changes are within ranges of the predicate devices. In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between the Charter™ Guidewires (in its various configurations) and the predicate devices. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the predicate devices. The differences in construction between the Charter™ wire and the predicate devices raise no new issues of safety and effectiveness such that the Charter™ Guidewire is considered substantially equivalent to the predicate devices.
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995". The following bench tests were performed: - Tensile Strength - Torque Strength - Outer Diameter measurement - Torque Response - Catheter Compatibility - Coating Adherence/Coating Integrity - Tip Flexibility The results from these performance evaluations demonstrated that the Charter™ Guidewire met the acceptance criteria defined in the product specification and performed comparably to the predicate device. Biological Safety of the device has been established through biocompatibility testing carried out in compliance with ISO 10993-1 under VP-0427 The following biocompatibility tests were performed

Test Description	Test Method
Cytotoxicity Study	Qualitative Evaluation – Dye Exclusion & Microscopial Evaluation
Cytotoxicity Study	Quantitative Evaluation - MTT or XTT Assay
Irritation Test	Intracutaneous Injection (ISO10993-10)
Sensitisation Test	Kligman Maximisation (ISO10993-10)

	Acute Systemic Toxicity Test	Systemic Injection ISO10993-11
	Acute Systemic Toxicity Test	ISO-Rabbit-Pyrogen
	Haemocompatibility Test	Haematology: Haemolysis – rabbit blood– Direct (Complete ASTM Method)
	Haemocompatibility Test	Haematology: In-vitro Haemocompatiblity Assay
	Haemocompatibility Test	Coagulation: The Prothrombin Time Assay (PT)
	Haemocompatibility Test	Coagulation: The Unactivated Partial Thromboplastin Time Assay (UPTT)
	Haemocompatibility Test	Thrombosis: In Vivo Thrombogenicity in Dogs
	Haemocompatibility Test	Complement Activation
	Haemocompatibility Test	Lee& White Coagulation Assay
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the Charter™ Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Brivant, LTD.
c/o Mr. Tomas Furey
Operations Manager
Parkmore West Business Park
Galway
Ireland

MAY 18 2011

Re: K103377
Trade/Device Name: Charter Guidewire Model 45-281, 45-282, 45-283
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter, Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: April 14, 2011
Received: April 18, 2011

Dear Mr. Furey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103377

Device Name: Charter Guidewire

Indications For Use: Charter Guidewires are intended for use in the coronary and peripheral vasculature.

Contraindications: The Charter Guidewire is not intended for use in the cerebral vasculature. Patients judged not acceptable for percutaneous intervention (PCI).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103377